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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,797	12/17/2001	Andrei L. Gindilis	671350-7	5839
27162	7590	03/04/2004		
CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI, STEWART & OLSTEIN 5 BECKER FARM ROAD ROSELAND, NJ 07068			EXAMINER CHIN, CHRISTOPHER L.	
			ART UNIT 1641	PAPER NUMBER

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,797

Applicant(s)

GINDILIS, ANDREI L.

Examiner

Chris Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I – claims 1-13 in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The disclosure is objected to because of the following informalities:
 - a.) The status of the parent application cited on page 1 of the specification needs to be updated.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague. The recitation of "a binder" in line 4 is not clear as to what the "binder" binds to. It is suggested that -- specific for the analyte -- be inserted after "a binder". In line 11, the recitation of "said measurement" lacks antecedent support. Lines 10-11 are confusing because it recites using only the working electrode but the previous

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lines requires the use of both the working and reference electrodes to determine the potentiometric response.

Claims 3-5 are vague because the recitation of "said labeled detection compound" in each claim lacks antecedent support.

Claim 8 is vague. The recitation of "said electrocatalytic enzyme" lacks antecedent support. Also, -- is -- should be inserted after "enzyme".

Claims 9 and 10 are vague. In line 1 of each claim, the recitation of "said electrocatalytic enzyme" lacks antecedent support.

Claim 11 is vague. In line 1, the recitation of "the diffusion medium" lacks antecedent support.

Claim 12 is vague. In line 1, the recitation of "the diffusion medium" and in line 2, the recitation of "the electrocatalytic enzyme" lack antecedent support.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 1 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Heller et al in light of Keen.

Heller et al (U.S. Patent 6,251,260) discloses a potentiometric sensor and method for analyte determination. One example of the sensor is a glucose sensor that includes a working electrode with a film that has a redox polymer that electrically connects reaction centers of an enzyme (i.e. a binder), such as glucose oxidase, to the electrode. After a potential pulse is applied to the enzyme electrode so that the electrode-bound redox centers are electrooxidized, the floating electrode potential decays to a value that varies linearly with the concentration of analyte glucose (see col. 2, lines 1-18). The potential is measured either continuously or repeatedly (see col. 4, lines 8-10). Figure 1 shows a potentiometric sensor (100) comprising a working electrode (102), a counter electrode (104), and a reference electrode (106). The working electrode (102) typically has a film (not shown) coating the surface of the electrode. The film may contain a catalyst, such as an enzyme, that catalyzes the electrooxidation or electroreduction of the analyte. The working, counter, and reference electrodes are coupled to a detector to measure a potential at the working electrode after a switch (110) has been opened (see col. 6, lines 1-57).

The method disclosed in Heller et al is a potentiometric technique, as in the instant method, but does not specifically recite comparing the potentiometric response from the working electrode with the reference electrode wherein a difference indicates the presence and concentration of analyte.

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However, Keen (U.S. Patent 6,060,327) discloses that potentiometric techniques monitor potential changes between a working electrode and a reference electrode in response to charged ion species generated from enzyme reactions on the working electrode (see col. 4, lines 16-19).

While Heller et al does not specifically recite the comparison of potential in step (c) of the instant method, the step of comparing potential between the working electrode and reference electrode is inherent in the potentiometric method of Heller et al because Keen teaches that such comparisons in potential between the working and reference electrodes is conventional in potentiometric techniques.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,281,539 discloses an electrode sensor for continuous monitoring of an immunoassay but lacks a reference electrode.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is 571-272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher L. Chin
Primary Examiner
Art Unit 1641

March 1, 2004